AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00003	See Block 16C	OS257793	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
ASPR-BARDA	ASPR-BARDA	US DEPT OF HEALTH & HUMAN SERVICES	ASPR-BARDA02
200 Independence Ave., S.W.		ASST SEC OF PREPAREDNESS & RESPONSE	
Room 640-G		ACQ MANAGEMENT, CONTRACTS, & GRANTS	
Washington DC 20201		O'NEILL HOUSE OFFICE BUILDING	
		Washington DC 20515	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

CUE INC. 1524801
Attn: AYUB KHATTAK
CUE INC.
4980 Carroll Canyon RD
Suite 100
SAN DIEGO CA 92121

CODE 1524801 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

x 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201800016C

10B. DATED *(SEE ITEM 13)* 06/04/2018

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended. ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted ; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted , such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)* Net Increase: $7,828,422.00
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* FAR 43.103(a)

E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 27-1562193
DUNS Number: 016813796
The purpose of this mod is to add value and funding to CLIN 0001 in the amount of $7,828,422. The total value of CLIN 0001 increases from $14,000,000 to $21,828,422. Also provided is the updated Statement of Work (SOW) for CLIN 0001 dated April 24, 2020. The period of performance changes from June 4, 2018 - January 3, 2021 - To - June 4, 2018 - January 3, 2022.

All other terms and conditions remain unchanged

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
Ayub Khattak, CEO		WENDELL CONYERS	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Ayub Khattak	5/11/2020	Wendell Conyers -S Digitally signed by Wendell Conyers -S Date: 2020.05.13 14:43:37 -04'00'	05/13/2020
(Signature of person authorized to sign)		*(Signature of Contracting Officer)*	

NAME OF OFFEROR OR CONTRACTOR
CUE INC. 1524801

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Delivery Location Code: HHS/OS/ASPR HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201 US Period of Performance: 06/04/2018 to 01/03/2023 Change Item 1 to read as follows(amount shown is the obligated amount):				
1	ASPR-18-02838 -- Base period funds to Cue Health Inc for the development of a first-in-class reusable platform-based influenza in vitro diagnostic (IVD)test for in-home use. Delivery: 01/03/2021 Amount: $14,000,000.00 Accounting Info: 2018.199TWNQ.25106 Appr. Yr.: 2018 CAN: 199TWNQ Object Class: 25106 Funded: $0.00 Amount: $7,828,422.00 Accounting Info: 2020.1991079.25103 Appr. Yr.: 2020 CAN: 1991079 Object Class: 25103 Funded: $7,828,422.00				7,828,422.00

Contract No. HHSO100201800016C P00003
Cue Health, Inc

The purpose of the mod is to add value and funding to CLIN 0001 in the amount of $7,828,422. The total value of CLIN 0001 increases from $14,000,000 to $21,828,422. The period of performance changes from June 4, 2018 - January 3, 2021 –To- June 4, 2018 - January 3, 2022.

All other terms and conditions remain unchanged

CLIN	Budget	Status
0001 – Influenza A/B Development	$14,000,000	Awarded- June 4, 2018
0001 – Influenza A/B Development- Modification	$ 7,828,422	***POP Ends January 3, 2022***
Total CLIN 0001	**$21,828,422**	***POP Ends January 3, 2022***

Statement of Work (SOW) Dated April 24, 2020

CLIN0001 Cue Health Monitoring System with Cue Influenza Cartridge and Cue Health Mobile App and Cue Professional Mobile App

Objective

To accelerate the, validation, regulatory authorization, and commercialization of the over- the- counter (OTC) and professional point-of-care (POC)/CLIA Waived Cue Influenza Cartridge for use with the Cue Health Monitoring System and the Cue Health Mobile Application for lay users and for professional operators. Activities described herein will result in:

- Separate 510k submissions for the Cue Health Monitoring System with Cue Influenza Cartridge for OTC and POC/CLIA Waived claims
- Expected 510k clearances and commercial availability of both the OTC and professional products

PROJECT MANAGEMENT (WBS 1.1.1)

The Contractor shall provide for the following as outlined below:

- The overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;
- A principal investigator (PI) responsible for project management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors; the contract deliverables list identifies all deliverables and reporting requirements for this contract.
- Project manager(s) responsible for monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities; costs incurred; and program activities.
- A BARDA liaison responsible for effective communication with the project officer and contracting officer.
- Administrative/legal staff to provide development of compliant subcontracts, consulting, and other legal agreements, and ensure timely acquisition of all proprietary rights, including IP rights, and reporting all inventions made in the performance of the project.
- Administrative staff with responsibility for financial management and reporting on all activities conducted by the contractor and any subcontractors.

ANALYTICAL STUDIES (WBS 1.1.2). Specific tasks include: preparation of study protocols, execution of studies and preparation of study reports for limit of blank, limit of detection, precision, reactivity/inclusivity, cross-reactivity, potentially interfering substances, specimen matrices, specimen stability, carryover, cartridge stability, flex studies, cartridge shipping stability, QC controls, other studies as required or requested by FDA in support of 510k clearance. Deliverable is a report for each analytical study.

CLINICAL (WBS 1.1.3):

In support of 510k clearance for the OTC claim, Cue will conduct clinical studies to generate data for:

- Repeatability/Reproducibility at external clinical sites
- Detection of Samples at the Limit of Detection at clinical sites

- Method Comparison of OTC Cue Influenza to a predicate FDA-cleared Influenza A/B NAT assay with enrolled subjects (lay users self-testing and enrolled parents testing their enrolled children) at clinical sites in a simulated at-home environment

In support of 510k clearance for the professional POC/CLIA Waived claim, Cue will conduct clinical studies to generate data for:

- Repeatability/Reproducibility at external clinical sites (same study as for OTC claim)
- Detection of Samples at the Limit of Detection at clinical sites (same study as for OTC claim)
- Method Comparison of POC/CLIA Waived Cue Influenza to a predicate Influenza A/B NAT assay with professional untrained operators testing enrolled subjects (includes parent testing his/her child)

Further description of the studies that will be conducted as part of the clinical validation of Cue Influenza at external clinical sites is presented below.

WBS/IMS Task 1.1.3.6: Clinical Study Protocols, Statistical Analysis Plans, Data Management Plans and eDatabase. Specific activities include preparation of OTC and POC/CLIA Waived Method Comparison, Reproducibility/Repeatability Study, and Samples at LoD Study Protocols (WBS 1.1.3.6.1); preparation of Statistical Analysis Plans (WBS 1.1.3.6.2); preparation of Data Management Plans(DMPs) and eDatabases (WBS 1.1.3.6.3 – 1.1.3.6.4). Deliverables are internal approval of OTC and POC/CLIA Waived Method Comparison, Reproducibility/ Repeatability Study, and Samples at LoD Study Protocols, SAPs, and DMPs, and live eDatabases.

WBS/IMS Task 1.1.3.7 – 1.1.3.8: Clinical Study Site and Central Lab Qualification and Selection for Method Comparison, Reproducibility/Repeatability, and Samples at LoD Studies. Specific activities include: development of site feasibility questionnaire, identification of potential sites, execution of non-disclosure agreement with potential investigators, conduct site qualification visits and reporting (WBS 1.1.3.7.1 – 1.1.3.7.8 and WBS 1.1.3.8.1 – 1.1.3.8.8).Deliverables are at least 16 clinical sites (8 sites for OTC and 8 sites for POC/CLIA Waived).

WBS/IMS Task 1.1.3.9: Clinical Study Site Contracts. Specific activities include: draft budgets and budget negotiation (WBS 1.1.3.9.1); draft contract and contract negotiations (WBS 1.1.3.9.2). Deliverables are clinical study contracts executed with clinical sites and central lab.

WBS/IMS Task 1.1.3.10: Institutional Review Board (IRB) Submissions and Approvals of Each Clinical Validation Protocol. Specific activities include selection of IRB, completion of IRB protocol submission forms, draft informed consent forms, and submission and approval of method comparison study protocols and informed consent forms (WBS 1.1.3.10.1 – 1.1.3.10.4). Deliverables are IRB approval of OTC and POC/CLIA Waived Method Comparison, Reproducibility/Repeatability Study, and Samples at LoD Protocols.

WBS/IMS Task 1.1.3.11: Clinical Study Materials. Specific tasks include: ship Cue IUO devices, mobile smart devices, predicate devices and sample collection kits procurement and accountability at clinical sites (WBS 1.1.3.11.1 – 1.1.3.11.7). Deliverables are all clinical study materials at the clinical sites.

WBS/IMS Task 1.1.3.12: Clinical Site Initiation. Specific tasks include: preparation of Clinical Monitoring Plans, set up of Trial Master Files and Investigator Site Binders, creation of study- specific forms, conduct initiation visits and preparation and approval of initiation visit reports (WBS 1.1.3.12.1; 1.1.3.12.2.1 – 1.1.3.12.2.12). Deliverables are clinical sites initiated.

WBS/IMS Task 1.1.3.13.1 – 1.1.3.13.4: Clinical Sites Reproducibility/Repeatability Study Conducted and Reported. This study will demonstrate the reproducibility and repeatability of the Cue Influenza Cartridge assay. This study will be conducted at 3 external CLIA Waived clinical sites with 6 trained professional operators using identical panel members. The sample panel will contain 10 panel members. Two strains of influenza A virus and 1 strain of influenza B virus will be used to build the panel members. The influenza A virus panel members will contain high negative (<LoD; C20-80), low positive (LoD; C95), and moderate positive (2-3x LoD; C100) concentrations. The influenza B virus panel members will contain high negative (<LOD; C20-80), low positive (LoD; C95), and moderate positive (2-3x LoD; C100) concentrations. One panel member will be negative for influenza A and B viruses. At each site, 2 operators per day will conduct testing and each operator will perform one run per day. Each operator will test 3 replicates of each sample panel per run. Each site will conduct testing for 5 days. Each site will generate 30 results per sample for a total of 90 results per sample overall. Statistical analysis will include calculating percent agreement (compared to expected results based on panel member concentration) by panel member, by site and overall. Subtasks include: study execution (WBS 1.1.3.13.1.1 - 1.1.3.13.1.4); database lock, data review and analysis (1.1.3.13.2.1 – 1.1.3.13.2.8); study close-out (WBS 1.1.3.13.3.1 – 1.1.13.3.2); preparation of study report (WBS 1.1.3.13.4.1 – 1.1.3.13.4.5). Deliverable is reproducibility/repeatability study report.

WBS/IMS Task 1.1.3.13.5 – 1.1.3.13.7: Clinical Sites Testing of Samples with Influenza Concentrations near the LoD Conducted and Reported. This study will demonstrate the performance of Cue Influenza Cartridge with untrained professional users testing samples with influenza virus concentrations near the limit of detection. The study will be conducted at 3 external CLIA Waived clinical sites. Cue will prepare a contrived weak positive (C95) sample pool and a contrived weak negative (C5) sample pool for 2 influenza A strains and 2 influenza B strains (one from each lineage) detected by Cue Influenza and distribute aliquots of the pools to the sites for testing. At least 2 untrained operators at each site will conduct testing. For weak positive samples, the percent of Cue Influenza positive results will be calculated overall and by site. For weak negative samples, the percent of Cue Influenza negative results will be calculated overall and by site. Specific activities include: study execution (WBS 1.1.3.13.5.1 – 1.1.3.13.5.4); database lock, data review and analysis (WBS1.1.3.13.6.1 – 1.1.3.13.6.8); study close-out (WBS 1.1.3.13.7.1 – 1.1.13.7.2); preparation of study report (WBS 1.1.3.13.8.1 – 1.1.3.13.8.5). Deliverable is Samples at LoD study report.

WBS/IMS Task 1.1.3.14: OTC and POC/CLIA Waived Method Comparison Studies.
The OTC and POC/CLIA Waived Method Comparison Studies will establish the clinical performance of the Cue Health Monitoring System with Cue Influenza Cartridge and Cue Health. Mobile Applications in comparison to a predicate influenza A/B NAT assay. The prospective, noninterventional method comparison studies will be conducted in parallel at a minimum of 10 US clinical sites. Participating sites will enroll subjects for both the OTC and POC/CLIA Waived studies; however, no subject may participate in both studies. The study population will include subjects of all ages with signs and symptoms of influenza virus infection. The OTC study will enroll lay users who will self-collect and self-test their own nasal swab sample using Cue Influenza and the Cue Health Mobile Application to generate data in support of the OTC claim. The OTC study will also enroll parents collecting and testing his/her enrolled child's nasal sample. In the POC/CLIA Waived study, professional untrained operators will test enrolled subjects (both adults and children) with Cue Influenza and the Cue Professional Mobile App to generate data in support of the POC/CLIA Waived claim. All predicate assay testing will be conducted by a professional trained operator in a CLIA Waived environment. The overall sample size is dependent on influenza prevalence during the clinical study, which varies by season, year and influenza type. The overall sample size across both the OTC and POC/CLIA Waived studies is approximately 4000 subjects, assuming a prevalence of approximately 5.5% for influenza B virus, to obtain a minimum of 220 samples

positive results for influenza A, 220 samples with positive results for influenza B, and 220 samples with negative results. Cue Influenza results will be compared to the predicate method (e.g., FDA-cleared influenza A/B NAT assay) and positive and negative percent agreement will be calculated. Specific activities include: study execution (WBS 1.1.3.14.1.1 – 1.1.3.14.1.6); database lock, data review and analysis (WBS 1.1.3.14.2.1– 1.1.3.14.2.10); study close-out (WBS 1.1.3.14.3.1 – 1.1.14.3.2); preparation of study report (WBS 1.1.3.14.4.1 – 1.1.3.14.4.5). Deliverable is method comparison study report.

WBS/IMS Task 1.1.3.15: BIMO Inspections. Specific activities include clinical site and Cue preparation and mock inspections (WBS 1.1.3.15.1 – 1.1.3.15.2). Deliverable is mock BIMO inspections completed.

REGULATORY (WBS 1.1.4):
WBS/IMS Tasks 1.1.4.1 – 1.1.4.3: Regulatory Submissions. Preparing and submitting FDA 510k for Cue Influenza OTC claim and FDA 510(k) for Cue Influenza POC/CLIA Waived claim. Deliverables are FDA 510k OTC and POC/CLIA Waived submissions and clearances.

WBS/IMS 1.1.6.13: Manufacture of Cue Influenza Cartridges for analytical and clinical validation. Manufacture of at least 3 lots of Cue Influenza Cartridges for analytical and clinical validation.

WBS/IMS 1.2.8: Quality: Maintenance of ISO 13485 certification, quality audits, instrument calibrations, QA and release batch records, design control records, oversee building management and any other records as required.

WBS/IMS 1.2.9 Operations: ERP, purchasing, supply chain and inventory management, production/quality team coordination.